



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:) Defect the Francisco	
Garlich et al.) Before the Examiner) Unknown	
Application No. 10/573,938) Group Art Unit) Unknown	
Filed March 30, 2006)	
CHELATE BASED SCAFFOLDS IN TUMOR TARGETING)) August 31, 2006	
INFORMATION DISC	CLOSURE STATEMENT	
Mail Stop Amendment Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450		
Commissioner:		
1. List of All Patents, Publications, U.S. Applic	ations, or Other Information	
	97, and 1.98, Applicant requests consideration of the form(s) (commonly referred to as a PTO-1449 form) elow.	
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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, Fax No. (571) 273-8300 on the date indicated below.		
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<u>2.</u>	Encl	osed I	egible Copies	
	a.	A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed,		
		i.	Patent Office in prior U.S. Patent A	ach reference previously cited by or submitted to the application Serial No. from which the present application claims
		ii.	except, a copy is <u>not</u> provided for e identified below:	ach cumulative reference and enclosed reference
	b.	A co	opy of the specification and drawing	s for each cited unpublished U.S. application.
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<u>3.</u>	Concise Explanation of Relevance for Non-English Language Information			
For e	each no	n-Eng	glish language reference listed on the	e attached SB/08 form(s), reference is made to:
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	3d.	the concise explanation contained in the present application at page(s),		
	3e.	the concise explanation set forth in the attached English language abstract,		
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<u>5.</u>	Certi	fication- Statement Under 37 CFR 1.97(e)
	5a.	It is hereby certified that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
	5b.	A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.
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The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b). It is

believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

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Edward E. Sowers, Reg. No. 36,015

Woodard, Emhardt, Moriarty, McNett & Henry LLP

111 Monument Circle, Suite 3700 Indianapolis, Indiana 46204-5137

(317) 634-3456

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known		
Application Number	10/573,938	
Filing Date	March 30, 2006	
First Named Inventor	Joseph R. Garlich	
Group Art Unit		
Examiner Name		
Attorney Docket Number	48003-5	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T	
		TAI-PING D. FAN, RHYS JAGGAR and ROY BICKNELL – Controlling the vasculature: angiogenesis, anti-angiogenesis and vascular targeting of gene therapy;		
		JUDAH FOLKMAN – Angiogenesis in cancer, vascular, rheumatoid and other diseases; Nature Medicine, Volume 1, Number 1 1995		
		J. MARTIN BROWN and AMATO J. GIACCIA – The Unique Physiology of Solid Tumors: Opportunities (and Problems) for Cancer Therapy; Cancer Research 58, 1408-1416, April 1, 1998		
		BRAD ST. CROIX, CARLO RAGO, VICTOR VELCULESCU, GIOVANNI TRAVERSO, KATHARINE E. ROMANS, ELIZABETH MONTGOMERY, ANITA LAL, GREGORY J. RIGGINS, CHRISTOPH LENGAUER, BERT VOGELSTEIN, KENNETH W. KINZLER – Genes Expressed in Human Tumor Endothelium; Science; 08/18/2000, Vol. 289 Issue 5482, p1197, 6p, 1 graph, 2c		
		STEPHEN J. KENNEL and SAED MIRZADEH – Vascular Targeted Radioimmunotherapy with ²¹³ Bi-An α –Particle Emitter; Nuclear Medicine & Biology, Vol. 25, pp. 241-246, 1998		
		STEVEN DICKMAN – Antibodies Stage a Comeback in Cancer Treatment; Science; 05/22/98, Vol. 280 Issue 5367, p1196, 2p, 1 graph, 1bw		
		MARCIA BARINAGA – A Surprising Partner for Angiostatin; Science; 03/19/99, Vol. 283 Issue 5409, p1831, 5/6p, 1c		
		WADIH ARAP, RENATA PASQUALINI, ERKKI RUOSLAHTI – Cancer Treatment by Targeted Drug Delivery to Tumor Vasculature in a Mouse Model; Science Vol. 279, January 16, 1998		
		RENATA PASQUALINI, ERKKI KOIVUNEN, ERKKI RUOSLAHTI – α v Integrins as receptors for tumor targeting by circulating ligands; Nature Biotechnology, Volume 15, June 1997		
		WADIH ARAP, RENATA PASQUALINI, ERKKI RUOSLAHTI – Chemotherapy targeted to tumor vasculature; Cancer Research Center, The Burnham Institute		
, ,		RENATA PASQUALINI – Vascular targeting with phage peptide libraries; The Quarterly Journal of Nuclear Medicine, Vol. 43, No. 2		
		D. BIOK et al. – Peptide adiopharmaceuticals in nuclear medicine; European Journal of Nuclear Medicine, Vol. 26, No. 11, November 1999		
		WYNN A. VOLKERT, TIMOTHY J. HOFFMAN – Therapeutic Radiopharmaceuticals; 1999 Am. Chem. Soc. Published on Web 8/11/1999		
		KARL GADEMANN, MARTIN ERNST, DANIEL HOYER, DIETER SEEBACH – Synthesis and Biological Evaluation of a Cyclo-\(\beta\)-tetrapeptide as a Somatostatin Analogue; Angew. Chem. Int. Ed. 1999, 38, No. 9		

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Examiner Signature	, in the second	Date Considered	

Substitute for form 1449B/PTO

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Sheet Attorney Docket Number 48003-5 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published Examiner Initials* RALPH HIRSCHMANN, K.C. NICOLAOU, SHERRIE PIETRANICO, JOSEPH SALVINO, ELLEN M. LEAHY, PAUL A. SPRENGELER, GEORGE FURST, AMOS B. SMITHIII, CATHERINE D. STRADER, MARGARET A. CASCIERI, MARIALUISA R. CANDELORE, CINDY DONALDSON, WYLIE VALE, LAURIE MAECHLER - Nonpeptidal peptidomimetics with a β-D-Glucose Scaffolding. A Partial Somatostatin Agonist Bearing a Close Structural Relationship to a Potent, Selective Substance P Antagonist; 1992 Am Chem. Society K. C. NICOLAOU, JOHN I. TRUJILLO, KELLY CHIBALE - Design, Synthesis and Biological Evaluation of Carbohydrate-Based Mimetics of cRGDFV; Tetrahedron, Vol. 53, No. 26, pp. 8751-8778, 1997 MARK W. PECZUH, ANDREW D. HAMILTON - Peptide and Protein Recognition by Designed Molecules; 2000 Am. Chem. Soc., Published on Web 06/20/2000 ROLAND HAUBNER, HANS-JURGEN WESTER, UTE REUNING, REINGARD SENEKOWITSCH-SCHMIDTKE, BEATE DIEFENBACH, HORST KESSLER, GERHARD STOCKLIN, MARKUS SCHWAIGER; Radiolabeled $\alpha_{\nu}\beta_{3}$ Integrin Antagonists: A New Class of Tracers for Tumor Targeting; J Nucl Med 1999; 40:1061-1071 B.R. LINE, P. WEBER, S. WURTHMAN, M. SALGAM, J.A. BENNETT - Intravascular Targeting of Tumor Angiogenesis Via TC-99M Radiolabeled Peptide Antagonists of the $\alpha_{\nu}\beta_{3}$ Integrin: Journal of Nuclear Medicine, Scientific Papers, Volume 40, Number 5, May 1999 RICHARD M. KEENAN, WILLIAM H. MILLER, CHET KWON, FADIA E. ALI, JAMES F. CALLAHAN, RAUL R. CALVO, SHING-MEI HWANT, KENNETH D. KOPPLE, CATHERINE E. PEISHOFF, JAMES M. SAMANEN, ANGELA S. WONG, CHUAN-KUI YUAN, WM. F. HUFFMAN – Discovery of Potent Nonpeptide Vitronection Receptor ($\alpha_{v}\beta_{3}$) Antagonists; 1997 Am. Chem Society, Volume 40, Number 15 CHRISTOPHER P. CARRON, DEBRA M. MEYER, JODI A. PEGG, V. WAYNE ENGLEMAN, MAUREEN A. NICKOLS, STEVEN L. SETTLE, WM. F. WESTLIN, PETER G. RUMINSKI, G. ALLEN NICKOLS – A Peptidomimetic Antagonist of the Integrin $\alpha_{\nu}\beta_{3}$ Inhibits Leydig Cell Tumor Growth and the Development of Hypercalcemia of Malignancy; Cancer Research 58. 1930-1935, May 1, 1998 R. HAUBNER et al. - Synthesis and First Evaluation of a SAA-Labeled RGD-Peptide for Monitoring the $\alpha_{\nu}\beta_{3}$ Integrin Expression; Journal of Nuclear Medicine, Sunday June 4, 2000 M. BOCK et al. – 99M Tc-, 188 Re- AND 90 Y-Labeled $\alpha_{\nu}\beta_{3}$ Antagonists: Promising Tracer For Tumor Induced Angiogenesis; Journal of Nuclear Medicine, Volume 41, Number 5, 5/2000 Supp. ANGELA WONG, SHING MEI HWANG, PATRICK MCDEVITT, DEAN MCNULTY, JEFFREY M. STADEL, KYUNG JOHANSON – Studies on $\alpha_{\nu}\beta_{3}$ Ligand Interactions Using a [3 H]SK&F-

107260 Binding Assay, Am. Soc. for Pharmacoloty and Experimental Therapeutics

Substitute for form 1449B/PTO

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OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner	Cito		Τ.
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-Issue number(s) publisher city and/or country where published	T ²
		PETER CARAVAN, JEFFREY J. ELLISON, THOMAS J. MCMURRY, RANDALL B. LAUFFER	
		- Gadolinium (III) Chelates as MRI Contrast Agents: Structure, Dynamics, and Applications;	
		1999 Am. Chem. Society, Published on Web 08/20/1999 A.K. RAPPE, C.J. CASEWIT, K.S. COLWELL, W.A. GODDARD III, W.M. SKIFF – UFF, a Full	╀
		Periodic Table Force Field for Molecular Mechanics and Molecular Dynamics Simulations; 1992 Am. Chem. Society, 114, 10024-10035	
		MARTIN J. O'DONNELL, CHANGYOU ZHOU, WM. L. SCOTT – Solid-Phase Unnatural	-
		Peptide Synthesis (UPS); J. Am. Chem Soc. 1996, 118, 6070-6071	
		WM. F. SCOTT, CHANGYOU ZHOU, ZHIQIANG FANG, MARTIN J. O'DONNELL - The Solid	
		Phase Synthesis of α,α-Disubstituted Unnatural Amino Acids and Peptides (di-	Ì
		UPS); Tetrahedron Letters, Vol. 38, No. 21, pp. 3695-3698, 1997	
		DAVID L. GRIFFITH, MARTIN J. O'DONNELL, RICHARD S. POTTORF, WM. L. SCOTT,	+
		JOHN A. PORCO, JR Tandem UPS: Sequential Mono- and Dialkylation of Resin-Bound	
		Glycine via Automated Synthesis; Tetrahedron Letters, Vol. 38, No. 51, pp. 8821-8824, 1997	
		MÁRTIN J. O'DONNELL, FRANCISCA DELGADO, RICHARD S. POTTORF -	T
		Enantioselective Solid-Phase Synthesis of α-Amino Acid Derivatives; Tetrahedron 55 (1999)	
		6347-6362	
		STU BORMAN – Multivalency: Strength in Numbers; Chemical & Engrg. News: Volume 78,	
		Number 41, October 9, 2000	\perp
		MATHAI MAMMEN, SEOK-KI CHOI, GEORGE M. WHITESIDES - Polyvalent Interactions in	
		Biological Systems: Implications for Design and Use of Multivalent Ligands and Inhibitors;	
		Angew. Chem. Int. Ed. 1998, 37, 2754-2794 KEVIN BURGESS, DONGYEOL LIM, SHAKER A. MOUSA – Synthesis and Solution	+
		Conformation of Cyclo: A Cyclic Peptide with Selectivity for the $\alpha_{\nu}\beta_3$ Receptor; 1996 Am. Chem. Society, October 1, 1996, 4520-4526	
		KEITH ROSE and JEAN VIZZAVONA – Stepwise Solid-Phase Synthesis of Polyamides as Linkers; J. Am Chem. Soc. 1999, 121, 7034-7038	
		ERKANG FAN, ZHONGSHENG ZHANG, WENDY E. MINKE, ZHENG HOU, CHRISTOPHE	
		L.M.J. VERLINDE, WIM G.J. HOL – High-Affinity Pentavalent Ligands of Escherichia coli	
		Heat-Labile Enterotoxin by Modular Structure-Based Design; J. Am Chem Soc. 2000, 122,	
		2663-2664 PAVEL I. KITOV ET AL. – Shiga-Like toxins are neutralized by tailored multivalent	╁
		carbohydrate ligands; Nature, Volume 403, 10 Feb. 2000	
		JEFFREY W. SMITH, DAVID A. CHERESH – The Arg-Gly-Asp Binding Domain of the	+
		Vitronectin Receptor; Journal of Biological Chemistry, Vol. 263, No. 35, 12/15/1988, pp.	
		18726-18731	
		FRANCESC MITJANS et al. – An anti-αν integrin antibody that blocks integrin function	
		inhibits the development of a human melanoma in nude mice; Journal of Cell Science 108,	
		2825-2838 (1995)	
		ROBERT PYTELA et al. – Platelet Membrane Glycoprotein Ilb/Illa: Member of a Family of	
	<u> </u>	Arg-Gly-Asp-Specific Adhesion Receptors; Science Vol. 231, March 28, 1986	\perp

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Examiner	Date
Signature	Considered

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